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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,769	11/30/2001	Peter Craig Farrell	P 282769 P034US2	5358

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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 12/10/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,769

Applicant(s)

FARRELL ET AL.

Examiner

Joseph F Weiss Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8-9 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A means for identifying acute phase of stroke is critical or essential to the practice of the invention, but is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

In regards to claim 8, the written description does not disclose a **means** for identifying patient characteristics of stroke in an acute phase of stroke, which is required to satisfy 35 USC 112(6).

In regards to claim 9, the written description does not disclose an instruction **means** associated with a delivery means for describing using said delivery means during an acute phase of an incident of stroke in a patient, which is required to satisfy 35 USC 112(6).

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. An instruction means is was not disclosed in the written

description when filed, hence such is new matter, furthermore such is not described in any manner to meet the written description standards.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 8 line 4, what is "its"?

Due to the lack of a properly recited means in the written description the claims are rendered indefinite

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Remmers in view of Zacouto (US 5305745).

Remmer substantially discloses the instant application's claimed invention to include a means for applying CPAP during the acute phase of a stroke, but does not explicitly disclose a means for identifying patient characteristics of a stroke. However, Zacouto disclose such (See any fig). The references are analogous since they are from the same field of endeavor, the medical arts. At the time the instant application's invention was made, it would have been

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obvious to one of ordinary skill in the art to have taken the device of Zacouto and used it in combination with the device of Remmers. The suggestion/motivation for doing so would have been to monitor the patient for stroke during ventilation of the user with CPAP to insure optimal oxygenation was retained throughout. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 10-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6336454. Although the conflicting claims are not identical, they are not patentably distinct from each other because both disclose the use of CPAP devices to treat stroke during acute phase, SPECIFICALLY:

A method for the treatment of a patient who is suffering a stroke, said method comprising: identifying the stroke in an acute phase, said acute phase being defined as the first three hours from onset of the stroke; and applying continuous positive airway pressure to said patient at least during said acute phase of said stroke in order to improve the patient's blood oxygen level, wherein said pressure is applied in a bi-level fashion.

Response to Arguments

1. Applicant's arguments filed 22 Sep 03 have been fully considered but they are not persuasive.

IN regards to the 35 USC 112(2) rejection based upon the absence of any disclosure whatsoever as to what applicant's "means" is/are, the amendment is proper and responsive, but not persuasive. The bald conclusion that one of ordinary skill in the art would simply be able to divine what applicant uses as a means to effectuate the functions is nothing more than random speculation. Absent an express disclosure of what the actual means is, applicant must prove with evidence what one of ordinary skill in the art would readily conclude what the means is immediately upon reading the disclosure, not just assert the empty conclusion that one of ordinary skill would come to the conclusion. IN regards to the examiner's use of a *Zacuto*, the examiner discharged his duties IAW the PTO policy of compact prosecution, to find references and make an art based rejection even when the claims do not meet the standards of 35

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USC 112. Zacuoto was found based upon a search of the recited functions and not from any disclosed means (due to the absence of any disclosure as to what the means is) therefore applicant's pointing to the rejection as implicitly meaning that one of ordinary skill in the relevant art is without merit, due to the rejection being based upon policy decision and not based upon what one of ordinary skill would determine.

Applicant by the nature/content of his argument admits on the record that no means is disclosed, but merely states the conclusion that one of ordinary skill would be able to identify the means by the content of this disclosure despite being devoid of disclosing a means. This is not how 35 USC 112(6) operates and fails to meet its minimum threshold standards of disclosure. Applicant's arguments are merely dressing up the fact that their disclosure fails 35 USC 112(6) by alleging, without the presentation of one scintilla of evidence as to the skill level and knowledge of the ordinary artisan, one of ordinary skill can conclude what comprises the means without it being disclosed. By not disclosing a means and instead leaving one of ordinary skill left totally unguided and compelling him to resort to completely random speculation as to what the means applicant is claiming is the very problem/issue that 35 USC 112 is meant to prevent, applicant admits by dint of the line of logic of their argumentation that they do not meet 35 USC 112 and thus the arguments are not persuasive.

In regards to the 35 USC 103 rejection, the arguments are moot in light of the fact applicant amended his claim language compelling a modification of the rejection.

In regards to the issue of modification, case law stipulates however, the current state of the law on motivation:

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2. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves **or in the knowledge generally available to one of ordinary skill in the art**. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

No where in the rejection does the examiner use applicant's disclosure to reach the obviousness conclusion. The rejection as written is a reasoned basis IAW 5 USC 555 and substantial evidence on the record as a whole has been presented to support the reasoned basis and conclusion of obviousness, hence unpatentability of the claims as they currently stand is proper and IAW the necessary legal burden of proof.

In regards to the issue that previously allowed claims that are later rejected need director level approval to be now rejected, claim 8 is not a linking claim under MPEP 806.05(e) because the claim is setting forth an apparatus having a means for identifying characteristics of stroke during acute phase which is not required for the methods of the parent application, thus claim 8 is properly rejected without a need for director authorization.

In regards to the double patenting rejection, it was not pre-mature under the PTO policy of compact prosecution.

Conclusion

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1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

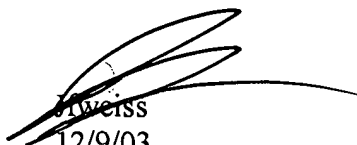
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.

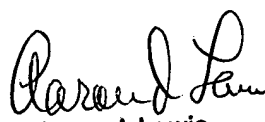
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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J. Weiss
12/9/03


Aaron J. Lewis
Primary Examiner